



06017.TF
688-560-256 811



05018.TF
688-560-256 III



05019.TF
688-560-256 SF



05020.TIF
712572256 冊



05021.TF
688-560-258 TF



05022.TF
688-560-253 TF



05023.TIF
712-572-256 10

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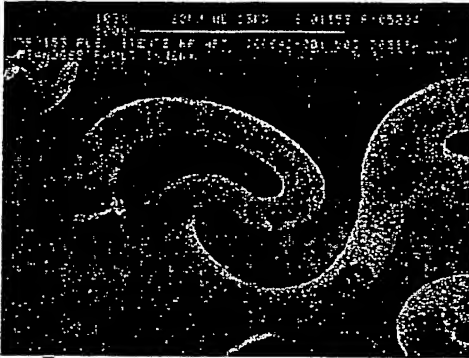


Fig 8

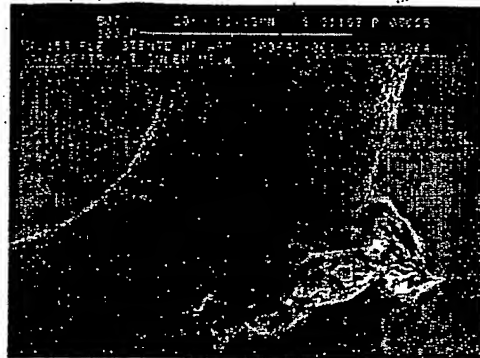
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Fig 9

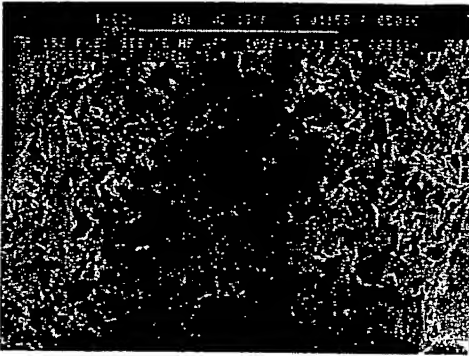
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Fig 10

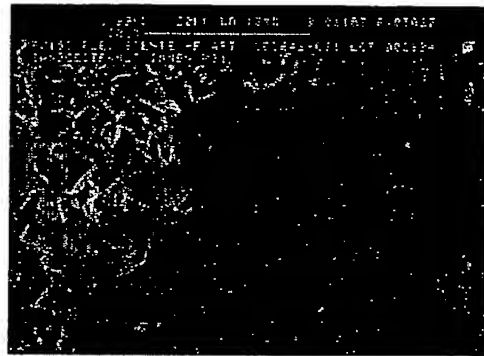
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Fig 11

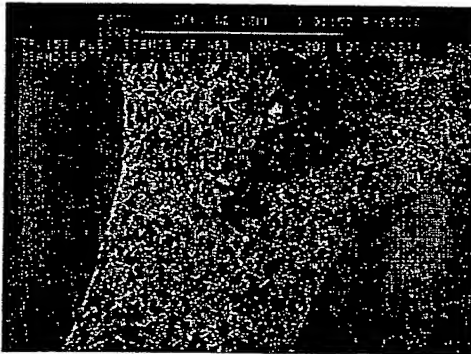
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Fig 12

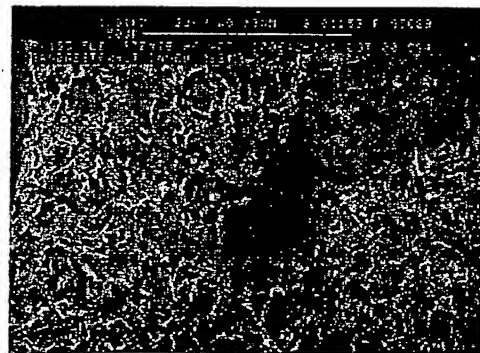
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Fig 13

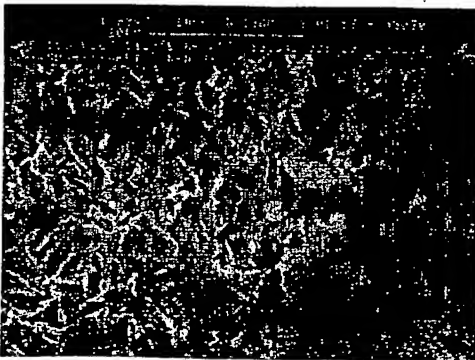
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Fig 14

05030.TIF
712-672-256.tif

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Figure 15

Lot # 094846
Article # 310S1835
Target dose 230 µg

	shipped	sample #
drug-content-RCC (3)	14.08.02	5971-5979
drug-release-RCC (3)	14.08.02	5980-5982
DMAC-RCC (1)	0	
samples for ageing		
samples for additional tests		

Table 1

= Felder für Einträge

Content - results
Date of content: 16.08.02

Table 2

Sample #	Target Dose [µg/Stent]	Content [µg/Stent]	Content mean [µg/Stent]	STDEV [µg]	CV [%]	Target Deviation [%]
5971		223				
5978	230	189	205	17,0	8,30	-10,7
5979		204				

Figure 16

Table 3

Release only [µg]	% Release of content	Stent only* [µg]	% of content	Release+ Stent [µg]	% of content
99,0	48,2		0,0	99,0	48,2
107,0	52,1		0,0	107,0	52,1
111,0	54,1		0,0	111,0	54,1
105,7	51,5	0,0	0,0	105,7	51,5

*) extraction after release test

Release
CT Lots with new method
(pH6)

Single values (µg Tacrolimus)

Table 4

Wavelength: 210 nm

sample #	0.16	0.5	1	4	6	24	48	72	96
5980	17	19	12	14	6	15	12	3	1
5981	22	18	10	14	7	15	13	6	2
5982	27	18	8	14	6	15	13	7	2
Average	22,0	18,3	10,3	14,0	6,3	15,0	12,7	5,3	1,7

Figure 17

Accumulated values (µg Tacrolimus)

Table 5

1 = < 2 µg

sample #	0.16	0.5	1	4	6	24	48	72	96
5980	17	36	48	62	68	83	95	98	99
5981	22	40	50	64	71	88	99	105	107
5982	27	45	54	68	74	89	102	109	111
Average	22,0	40,3	50,7	64,7	71,0	88,0	98,7	104,0	105,7

Figure 18

